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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,447

09/02/2004

Augustinus Bader

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,447	Applicant(s) BADER, AUGUSTINUS	
	Examiner SHANTA G. DOE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42, 49-56 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63-66 is/are allowed.
- 6) ☐ Claim(s) 42, 49-56 and 67-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment/ Arguments

1. The amendment filed on November 19, 2007 has been received and considered for examination. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 52 is rejected under 35 U.S.C. 102(b) as being anticipated by Lee (US 4,377,639).

Regarding claim 52, Lee discloses a device for raising or cultivating cells in a container-like receptacle which comprises: a base (13); and at least an upper lid (12), wherein the upper lid (12) is connected to the receptacle (11) in a pressure-tight manner, and the receptacle (11) or the upper lid (12) is provided with at least one inlet bore for one of the introduction and withdrawal of culture medium and oxygen (the receptacle 11 has ports 21, 22 and 23 with bores within the ports), and at

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least one resilient lateral tensioning ring (29) encircles at least the receptacle (11) and the upper lid (12) to retain the upper lid (12) in sealing engagement with the receptacle (11) when the receptacle (11) is rotated about a transverse axis (see abs., Fig 1, col. 1 lines 34 – 43, col. 2 lines 20 -46).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 4,377,639).

Regarding claim 42, Lee discloses a device for raising or cultivating cells in a container-like receptacle, the device comprising:

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a cylindrical middle part (11) of the device being closed off at a top by an upper lid (12) and a lower lid (13) which forms a base of the receptacle (11), at least one inlet bore (bore within port 21, 22 and 23) for one of an introduction and a withdrawal of culture medium and oxygen, and wherein the upper lid (12) and the lower lid (13) are connected to the middle part in a pressure-tight manner wherein the upper and the lower lids (12, 13) and the middle part are connected to one another by mating internal and external threaded connections (24,26), and each threaded connection is provided with at least one sealing ring (29) (see abs., Fig 1, col. 1 lines 34 – 43, col. 2 lines 20 - 46).

Lee fails to disclose that the bores are located on the upper lid and the lower lid of the device.

However, it would have been obvious to one having ordinary skill in the art to have at least bore located on the lower and upper lid of the device of Lee, since it has been held that rearranging parts of an invention involves only routine skill in the art. (See MPEP 2144.04)

Regarding claim 49, Lee discloses the device as claimed in claim 42 wherein the upper lid (12) and the lower lid (13) are each provided with an extension ring (28), at least partially enclosing the cylindrical middle part sealingly from the outside.

Regarding 51, Lee discloses the device as claimed in claim 49, wherein the extension rings (28) each seal off the middle part from the outside via a threaded connection(see fig 1).

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 4,377,639) as applied to claim 49 above, and further in view of Waggoner (US 1,337, 981).

Regarding claim 50, Lee discloses the device as claimed in claim 49. However, Lee fails to disclose the device of claim 49 wherein the extension rings each seal off the middle part from the outside via a clamp connection.

Waggoner (US 1,337, 981) discloses that it is known to secure a cover (lid) to a receptacle using a clamp (see fig.1; lines 70 - 73)

In view of Waggoner, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the secure coupling/connection means between the lids and the middle part of the Lee reference with the clamp connection means as taught by Waggoner, because the substitution of one known connecting means for another would have yielded a predictable result of coupling the lid to the middle part in a secure manner.

8. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 4,377,639) as applied to claim 49 above, and further in view of Willemsen (US 2004/0020889).

Regarding claim 50, Lee discloses the device as claimed in claim 49. However, Lee fails to disclose the device of claim 49 wherein the extension rings each seal off the middle part from the outside via a clamp connection.

Willemsen discloses a cap with extension rings for an airtight seal of a container such as a jar, wherein the cap could be coupled to the container by means of a clamp connection (see Willemsen para. [0021] lines 5 and 6).

In view of Willemsen, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the secure coupling/connection means between the lids and the middle part of the Lee reference with the clamp connection means as taught by Willemsen, because the substitution of one known connecting/coupling means for another would have yielded a predictable result of coupling the lid to the middle part in a secure manner.

9. Claims 53, 56, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christian et al (US 5,267,791) in view of Winston et al (US 4,851,354).

Regarding claim 67, Christian discloses a device for raising or cultivating cells in a container-like receptacle which comprises a base (4); and at least one lid (2), wherein the at least one lid (2) is connected to the receptacle in a pressure-tight manner, and the receptacle or the at least one lid (2) is provided with at least one inlet bore (14) for one of the introduction and withdrawal of culture medium and oxygen (see Christian fig 1, and col. 3 lines 36 -54) . Christian fails to disclose that the receptacle is further provided with a pressurizing means included within a structure of elements for exerting pressure internally on the cells.

Winston et al discloses that it is known in the art for devices used in cultivating cell to have pressurizing means included within the a structure of elements for exerting pressure internally on the cell, specifically, Winston discloses a bioreactor comprising a base, a removable cap, reservoir coupled to the base wherein the reservoir is filled with pressurizing medium to create variations in hydrostatic pressure beneath the base thereby exerting pressure on the cell attached to the base (See Winston col.1 lines 42-57; col.2 lines 48 - 68).

In view of Winston, it would have been obvious to one having ordinary to one having ordinary skill in the art at the time of the invention to includes a pressurizing means within the cell cultivating device of Christian as taught by Winston since Winston states on col. 1 lines 43- 45 that such a modification would enable the device to mimic or reproduce the natural mechanical environment of the cells be cultivated.

Regarding claim 68, the combination as applied to claim 67 above discloses the device

as claimed in claim 67. The combination fails to disclose that the pressurizing means includes a movable film, plate or membrane arranged in the receptacle.

Winston et al further discloses that the pressurizing means includes base formed of polyetherurethane film which deforms to exert pressure on the cells (see Winston claim 2, col. 1 lines 55 -57; col. 2 lines 67).

In view of Winston, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the pressurizing means of the combined reference comprise a movable film, plate or membrane arranged in the receptacle as taught by Winston since, the substitution of one known means of pressurizing cells in a device for another would have yielded a predictable result of applying pressure to cell in order to mimic their in vivo environment.

Regarding claim 53, Christian in view Winston discloses the device as claimed in claim 67 wherein the device comprise a pressurizing means. The combination fails to disclose that the pressurizing means is formed of expandable elements.

Winston et al further discloses that the pressurizing means includes base formed of polyetherurethane film which deforms to exert pressure on the cells (see Winston claim 2, col. 1 lines 55 -57; col. 2 lines 67).

In view of Winston, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the pressurizing means of the combined reference be of expandable elements as taught by Winston, since it was known in the

art at the time for pressurizing means associated with cell culture device to be expandable elements.

Regarding claim 56, the combination as applied to claim 67 above discloses the device as claimed in claim 67, wherein the pressurizing means can subject an interior of the receptacle with the cells to alternating pressure loads (see Winston col. 1 lines 50-57).

10. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Christian et al (US 5,267,791) in view of Winston et al (US 4,851,354) as applied to claim 67 above, and further in view of Hung et al (US 2002/0106625).

Regarding claim 54, the combined reference as applied to claim 67 discloses the device as claimed in claim 67 wherein the device comprise a pressurizing mean. However, the combination fails to disclose that the pressurizing mean is designed as a cylinder/piston unit.

Hung (US 2002/0106625) discloses a cell culture device having pressurizing means wherein the pressurizing means is designed as a cylinder/piston unit (see Hung claim 37, fig. 1 & 3; para. [0057] & [0058])

In view of Hung, it would have been obvious to one having ordinary skill in the art at the time of the invention to have the pressurizing means of the combined reference be a cylinder/piston unit, since, the substitution of one known means of pressurizing

cells in a device for another would have yielded a predictable result of applying pressure to cell in order to mimic their in vivo environment.

Allowable Subject Matter

11. Claim 63-66 are allowed.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797